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25 *Bard Peripheral Vascular, Inc.*

16
17 **IN THE UNITED STATES DISTRICT COURT**
18
19 **FOR THE DISTRICT OF ARIZONA**

20 IN RE: Bard IVC Filters Products Liability
21 Litigation,

22 No. 2:15-MD-02641-DGC

23 **DEFENDANTS' REPLY IN
24 SUPPORT OF ITS MOTION FOR
25 SUMMARY JUDGMENT AS TO
PLAINTIFFS DEBRA AND JAMES
FRANCES TINLIN'S CLAIMS**

26 (Assigned to the Honorable David G.
27 Campbell)

28 **(Oral Argument Requested)**

When considering the admissible evidence in Bard's Motion and the plaintiffs' Response briefing¹ Bard submits that no reasonable jury could find, absent sheer speculation, any of the following:

- that an inadequate warning proximately caused Mrs. Tinlin's injuries;
- that either Mrs. Tinlin or Dr. Riebe relied on any misrepresentation/concealment or than any alleged misrepresentation/concealment caused any pecuniary loss;
- that a reasonable alternative design to the Recovery Filter could have reduced or avoided the harm to Mrs. Tinlin; or
- that many of Mrs. Tinlin's alleged future medical expenses are reasonably certain.

In short, the plaintiffs must produce evidence of a genuine dispute of material fact that could satisfy its burden at trial, and they have not satisfied this burden. *See Sonner v. Schwabe N. Am., Inc.*, 911 F.3d 989, 992 (9th Cir. 2018) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254-55 (1986)). As such, summary judgment is warranted.

I. The plaintiffs' warnings-based claims (Counts II and VII) fail as a matter of law on causation grounds.

As with this Court's summary judgment ruling in *Hyde* (Doc. 12007), the Court need not determine whether the learned intermediary doctrine applies in Wisconsin because, as in *Hyde*, the Court can decide Bard's Motion on the causation element of the plaintiffs' failure-to-warn claims.²

¹ As part of their response papers, the plaintiffs "incorporated by reference" a 52-page "Omnibus Separate Statement of Facts" (Doc. 7950). The District of Arizona Local Rule 56.1(b) does not require a moving party to reply to a "controverting statement of facts" or respond to a non-moving party's "additional facts." Accordingly, Bard is not filing such a reply or response here. As noted throughout this Reply Brief, however, these allegations do not raise a genuine issue of material fact that would preclude summary judgment.

² The Court should note that the plaintiffs incorrectly state Wisconsin law when they claim that "summary judgment should not be granted" when there is a factual dispute about whether a manufacturer "misrepresented and misled the medical community." (Pl. Resp. Br. (Doc. 15694) at 5 (citing *Garross v. Medtronic, Inc.*, 77 S. Supp. 3d 809, 817 (E.D. Wis. 2015).) *Garross* concerned a motion to dismiss where the plaintiff alleged facts that would undermine the applicability of Medtronic's sophisticated user defense,

1 **A. If Bard's duty to warn ran to Mrs. Tinlin, the plaintiffs cannot prove**
 2 **causation.**

3 If Bard had a duty to warn Mrs. Tinlin, as the plaintiffs claim,³ then summary
 4 judgment is warranted because the plaintiffs have not cited any evidence that Mrs. Tinlin
 5 would have forgone treatment with the Recovery Filter if provided information about the
 6 filter's risk profile. The only evidence that the plaintiffs cite to oppose summary
 7 judgment is as follows:

- 8 • Mrs. Tinlin argues that she thought she was receiving a permanent filter. (Pl.
 9 Resp. Br. (Doc. 15694), at 4.) Mrs. Tinlin's subjective belief about whether
 10 the filter was going to be placed permanently has no bearing on Bard's duty
 11 to warn or whether a different warning would have caused Mrs. Tinlin to
 12 forgo treatment with the Recovery Filter.
- 13 • Mrs. Tinlin argues that she does not remember being told "anything
 14 negative" about the filter. (*Id.*) Her testimony does not concern whether
 15 "anything negative" about the Recovery Filter would have changed her
 16 decision to be treated with the Recovery Filter.
- 17 • Mrs. Tinlin argues that "had she been given a choice, knowing the risks of
 18 retrievable filters, she would have chosen a permanent one." (*Id.*) The
 19 testimony that the plaintiffs cite, however, does not support the proposition

20 and the court declined to dismiss the cause of action before discovery. The plaintiffs also
 21 incorrectly claim that summary judgment is "inappropriate if there is any indication that a
 22 lack of information about risks existed in the doctor's mind." (Pl. Resp. Br. (Doc. 15694)
 23 at 5) (citing *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis.
 24 2009).) In *Forst*, the prescribing physician testified that he changed his prescribing
 25 behavior after learning additional information about Paxil, thus allowing the jury to
 26 reasonably infer that he would have changed his decision to prescribe Paxil to the plaintiff
 27 if the defendant had provided him with adequate warnings earlier. Neither case supports
 28 the sweeping propositions for which they are cited, and neither case precludes summary
 judgment on the Tinlins' failure-to-warn claims.

3 As discussed in Bard's Motion, the great weight of authority, including Seventh
 Circuit's recent *In re Zimmer* decision that recently analyzed this precise issue under
 Wisconsin law, supports application of the learned intermediary doctrine. (Mot. (Doc.
 15071) at 6-7 (discussing *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884
 F.3d 746 (7th Cir. 2018) (noting that at least 48 states' highest courts or intermediate
 appellate courts have applied or favorably cited the learned intermediary doctrine).)

1 **B. If Bard's duty to warn ran to Dr. Riebe, the plaintiffs cannot prove**
 2 **causation.**

3 The plaintiffs cite testimony that Dr. Riebe would have liked to have known
 4 numerous hypothetical pieces of information.⁵ But, even assuming that these hypothetical
 5 pieces of information are true, Dr. Riebe never testified or suggested that the information
 6 would have caused him to forgo use of the Recovery Filter for Mrs. Tinlin, and the
 7 plaintiffs identify no testimony to the contrary.

8 The plaintiffs then claim that "Dr. Riebe would have disclosed all of this
 9 information to Mrs. Tinlin" (Pl. Resp. Br. (Doc 15694) at 6.) But the plaintiffs do
 10 not identify any testimony of Dr. Riebe where he actually said or suggested that he would
 11 have shared any of this alleged information with Mrs. Tinlin. Because there is no
 12 testimony from Dr. Riebe saying or suggesting that he would have forgone use of the
 13 Recovery Filter for Mrs. Tinlin if Bard provided him with different or additional
 14 information (indeed, Dr. Riebe does not recall ever seeing the Recovery Filter IFU, and
 15 his practice is to throw Dear Doctor letters in the trash (*see* Mot. (Doc. 15071) at 7-8), the
 16 plaintiffs cannot establish that an alleged failure to warn proximately caused Mrs. Tinlin's
 17 injuries. *See, e.g., In re Zimmer*, 884 F.3d at 752-53 ("Even in the event that a warning is
 18 inadequate, proximate cause is not presumed.") (quoting *Kurer v. Parke, Davis & Co.*,
 19 679 N.W.2d 867, 876 (Wis. Ct. App. 2004); *Kurer*, 679 N.W.2d at 876 ("Absent proof
 20 that a more complete or explicit warning would have prevented [the plaintiffs] use of [the
 21 product], she cannot establish that Warner-Lambert's alleged failure to warn was the
 22 proximate cause of her injuries.") Accordingly, summary judgment on the plaintiffs'
 23 failure-to-warn claims is warranted.

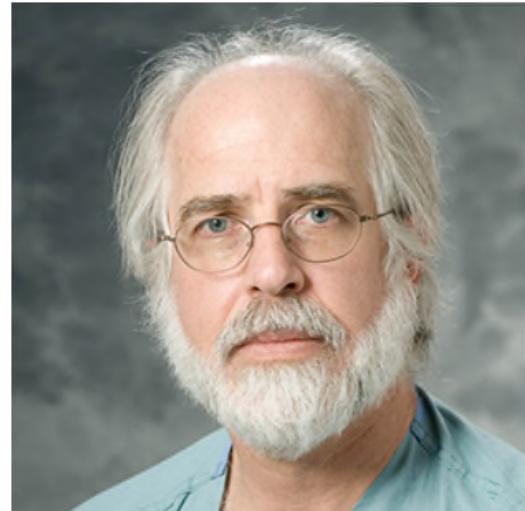
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 25
 26 ⁵ Bard believes that these questions of Dr. Riebe were improper because they both lacked
 27 foundation and were incomplete hypotheticals. Thus, Dr. Riebe's testimony should not be
 28 available to the plaintiffs in opposing summary judgment. Fed. R. Civ. P. 56(c)(2) ("A
 party may object that the material cited to support or dispute a fact cannot be presented in
 a form that would be admissible in evidence.").

1 **II. The plaintiffs' negligent and fraudulent misrepresentation/concealment claims**
 2 **(Counts VIII, XII, XIII) and claim for violation of Wisconsin law (Count XIV)**
 3 **fail as a matter of law because the plaintiffs cannot prove reliance or**
 4 **causation.**

5 To prove that Dr. Riebe relied on a false representation by Bard (fraudulent
 6 misrepresentation), relied on an untrue representation of fact by Bard (negligent
 7 misrepresentation), and/or relied on an undisclosed material fact by Bard (fraudulent
 8 concealment), the gravamen of the plaintiffs' argument is that a year before Mrs. Tinlin
 9 received the Recovery Filter, Bard allegedly provided misleading information to Dr.
 10 Riebe's mentor, Dr. John McDermott, a professor at the University of Wisconsin Medical
 11 School, via an e-mail; and Dr. Riebe relied on risk-benefit information from those who
 12 trained him (i.e., Dr. John McDermott). Thus, the plaintiffs' argument goes, the jury can
 13 reasonably infer that the misrepresented information provided to Dr. McDermott was
 14 passed along to Dr. Riebe, and Dr. Riebe relied on that information in choosing the
 15 Recovery Filter for Ms. Tinlin. (Pl. Resp. Br. (Doc. 15694), at 7.) But the e-mail that the
 16 plaintiffs cite to show this alleged misrepresentation did not involve Dr. John McDermott,
 17 the interventional radiologist who has practiced medicine at the University of Wisconsin
 18 for over thirty years with Dr. Riebe. Rather, the e-mail involves Mr. John McDermott, the
 19 former President of Bard Peripheral Vascular.⁶ As counsel for the plaintiffs knows,⁷ these
 20 John McDermotts are different people:

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 23 ⁶ The e-mail at issue is attached as Exhibit 2 to the Plaintiffs' Controverting Statement of
 24 Facts. That version of the e-mail does not identify the e-mail addresses of the authors and
 25 recipients, but another version of the same e-mail that Bard has produced contains this
 26 information. (E-mail from D. Ciavarella to J. McDermott, June 2, 2004, BPVE-01-
 27 00163350-52, excerpt attached as Exhibit A.) For John McDermott, the e-mail address is
 28 John.McDermott@crbard.com.

29 ⁷ Indeed, Ramon Lopez, whose name is on the signature block of the Response Brief
 30 deposed John McDermott, former President of BPV. The very first question that Mr.
 31 Lopez asked Mr. McDermott was whether he was a doctor: "Q. Mr. McDermott, right,
 32 not Dr.? A. No. Q. Okay. A. Mr. is fine." (McDermott Dep. Tr., 9:14-17, Feb. 5, 2014,
 33 attached as Exhibit B.)



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11 *Compare* John McDermott LinkedIn Profile, at <https://www.linkedin.com/in/jdmcdermott>
12 (last visited Mar. 8, 2019), *with* John McDermott, M.D., University of Wisconsin
13 Department of Radiology Faculty Profile, at <https://www.radiology.wisc.edu/profile/john-mcdermott-35/> (last visited Mar. 8, 2019).)

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15 Moreover, the face of the e-mail that the plaintiffs cite further makes clear that the
16 former President of BPV, and not an interventional radiologist from the University of
17 Wisconsin, was the author and recipient. Mr. McDermott wrote to various high-level
18 Bard employees, “*we* have had several discussions with physicians about bariatric patients
19 and *I*’ve asked *our Filter team* to summarize what we know to date. We’ll pull this
20 information together for you over the next week. Also, we’ll provide you with a 1 page
21 summary of *our filter complaints/shipments.*” (Ex. 2 to Pl. Controverting Statement of
22 Facts (emphasis added).) Mr. McDermott then asks Dr. Ciavarella to please copy
23 numerous other BPV employees on all messages and discussions about the filter, which
24 Dr. Ciavarella then apologizes for not having done previously. (*Id.*)

25 Thus, the linchpin in the plaintiffs’ argument relies on a case of mistaken identity
26 between the former President of BPV and the interventional radiologist at the University
27 of Wisconsin who share the same name. As such, the plaintiffs have no evidence to
28 satisfy the reliance element of their claims, and summary judgment is warranted.

1 Finally, although the plaintiffs argue that they need not prove reliance to reach the
 2 jury under Wisconsin Statute section 100.18, they must prove that Bard made false or
 3 misleading claims that *caused* the plaintiffs to suffer a pecuniary loss. *Valente v. Sofamor*,
 4 *S.N.C.*, 48 F. Supp. 2d 862, 874 (E.D. Wis. 1999). The plaintiffs have not identified any
 5 evidence as to how the specifically alleged “misleading statements to the public at large,
 6 and to doctors specifically,” (Pl. Resp. Br. (Doc. 15694), at 9), *caused* the plaintiffs to
 7 suffer a pecuniary loss. As such, summary judgment is warranted.

8 **III. The plaintiffs’ design-based claims (Counts III and IV) fail as a matter of law
 9 because the plaintiffs have no admissible evidence of a reasonable alternative
 10 design.**

11 The plaintiffs argue that Dr. McMeeking’s opinions are sufficient to create a triable
 12 issue of fact regarding alternative design in *Tinlin* because of this Court’s ruling in *Hyde*.
 13 But several key differences exist in *Tinlin*. First, unlike in *Hyde*, Dr. McMeeking
 14 specifically testified that the incorporation of any of his design changes to the Recovery
 15 Filter may not have prevented Mrs. Tinlin’s alleged injuries. (McMeeking Dep. Tr., 56:23
 16 to 59:7; 60:13-21; 85:15-18, Jan. 30, 2019, attached as Exhibit C.) Second, unlike in
 17 *Hyde*, Dr. McMeeking specifically testified that he cannot say whether the Simon Nitinol
 18 Filter, Greenfield Filter, Gunther Tulip Filter, Bird’s Nest Filter, or any other retrievable
 19 filter would have been a viable option for Mrs. Tinlin given her medical condition.⁸ (*Id.* at
 20 52:14 to 53:15.) Third, unlike in *Hyde* where the Court noted that Bard did not explain
 21 why incorporation of design features that Dr. McMeeking has also opined are defective
 22 should entitle Bard to summary judgment (Or. (Doc. 12007), at 13), Bard has provided
 23 such an explanation in *Tinlin*. (*See* Mot. (Doc. 15071), at 12 (discussing why a defective
 24 design cannot be a reasonable alternative design).) Thus, the Court’s ruling in *Hyde*
 25 should not control the outcome of Bard’s Motion in *Tinlin*.

26 _____
 27 ⁸ Nor would Dr. McMeeking be qualified to do so. *See* Or. on Mot. to Exclude Dr.
 28 McMeeking (Doc. 10051), at 10 (noting that both Bard and plaintiffs agree that Dr.
 McMeeking is not qualified to opine that the SNF would have been a safer alternative
 filter for any particular plaintiff).

1 The only evidence that the plaintiffs have cited in opposition to Bard’s design
 2 arguments is Dr. McMeeking’s opinions and several paragraphs from the “Omnibus”
 3 Statement of Facts. Bard has moved to exclude Dr. McMeeking’s opinions under Rule
 4 702, however, and has further explained why these opinions do not satisfy the plaintiffs’
 5 burden of proving that a reasonable alternative design existed *for Mrs. Tinlin* given her
 6 medical conditions and resulting damages. Moreover, the “Omnibus” Statement of Facts
 7 that the plaintiffs cite merely summarizes internal Bard documents, fact-witness
 8 testimony, and an opinion of Dr. Kessler that an apparent difference between the
 9 Recovery Filter and the SNF “erod[ed] Bard’s claim that the device was substantially
 10 equivalent to the SNF.” (Pl. Resp. Br. (Doc. 15694), at 10 n.2.) These “facts” do not say
 11 anything about a reasonable alternative design to the Recovery Filter that would have
 12 reduced the risk of Mrs. Tinlin’s injuries. Thus, the plaintiffs have failed to identify
 13 admissible evidence to establish a reasonable alternative design suitable for Mrs. Tinlin.

14 Finally, the plaintiffs argue that the SNF should constitute a reasonable alternative
 15 design because of the Court’s analysis of *Oden* in *Hyde*. The plaintiffs, however, do not
 16 address Bard’s argument: that Dr. Riebe, at the relevant point in time that he chose a filter
 17 for use with Mrs. Tinlin, specifically and unequivocally testified that he thought that Mrs.
 18 Tinlin was a candidate for a retrievable filter. (SOF (Doc. 15073) ¶ 5.) This unequivocal
 19 testimony was missing from *Hyde* and should change the Court’s analysis where the SNF
 20 has no option to be retrieved once placed. And Dr. Riebe never testified that he would
 21 have used a permanent only filter for Mrs. Tinlin. As *Oden* recognizes, for an alternative
 22 design to be *reasonable*, it must have been an actual option for the plaintiff given the
 23 circumstances of the case. Where Dr. Riebe testified that he wanted to use a retrievable
 24 filter for Mrs. Tinlin, where he never testified that he would have used a permanent only
 25 filter for Mrs. Tinlin, and where the SNF is a permanent only filter, the SNF (or any other

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1 permanent only filter) cannot be a *reasonable* alternative design in Mrs. Tinlin's case.⁹

2 Accordingly, summary judgment on the plaintiffs' design claims is warranted.

3 **IV. Many of the plaintiffs' claims for future damages have an insufficient**
 4 **evidentiary basis to proceed to trial.**

5 Wisconsin law is clear that damages for future medical treatment are compensable
 6 only if those injuries are reasonably certain to occur. *See Meracle v. Children's Serv. Soc.*
 7 *of Wis.*, 437 N.W.2d 532 (Wis. 1989) (affirming the finding that the plaintiff could not
 8 have brought a cause of action in 1981 for Huntington's disease because, based on the
 9 information available in 1981, the plaintiff's chances of developing the disease were a
 10 "mere possibility" and therefore not "reasonably certain" to develop); *Helgerson v. Wal-*
 11 *Mart Stores, Inc.*, No. 2015AP1993, 2016 WL 5415965, at *1 (Wis. Ct. App. Sept. 29,
 12 2016) (affirming motion after verdict and dismissal order where the trial court reduced an
 13 award for future medical expenses for a surgery from \$30,000 to \$0 because the evidence
 14 "failed to establish to a reasonable certainty that future surgery would occur," noting that
 15 the plaintiff adduced "only evidence showing that the surgery was a medically reasonable
 16 option that was available to her" not that "future surgery was likely to occur"); *see also*
 17 *Hargrove v. Peterson*, 221 N.W.2d 875, 879 (Wis. 1974) ("To justify an assessment of
 18 damages for future or permanent disability, it must appear by the proofs offered and on

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20 ⁹ The plaintiffs' discussion of *Godoy v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 687 (Wis. 2009) is unpersuasive. First, the case was decided before the Wisconsin legislature enacted Wisconsin Statute section 89.047 in 2011. The statute clearly adopted different design defect standards than the *Godoy* Court discussed in 2009 (e.g., the requirement of a reasonable alternative design, which *Godoy* specifically rejects). Second, the court did not hold, as the plaintiffs claim, that the *only* way to challenge an alternative design is by proving that doing so is "akin to 'eliminating the product itself.'" Rather, *Godoy* involved a narrow question on a motion to dismiss in which the complaint alleged that "white lead carbonate pigment" paint was defectively designed because it contained lead. The Wisconsin Supreme Court found that there could be no "white lead carbonate pigment" paint without lead because such a paint would be "eliminating the product itself." Third, even if *Godoy* is still good law, then it supports Bard's argument that summary judgment is warranted because eliminating the ability of the Recovery Filter to be retrieved, as would be necessary to make it the SNF (or any other alternative filter that Dr. McMeeking identified), is tantamount to eliminating the product itself—removing the ability of the filter to be optional eliminates it from being an "optional" filter.

1 the record made that such continued or future disability is reasonably certain to result
 2 from the injuries sustained.”).

3 The plaintiffs fall short of their burden. Despite the plaintiffs’ argument, whether
 4 Drs. Hurst and Muehrcke offer opinions “to a reasonable degree of medical probability”
 5 that Mrs. Tinlin is at some risk of various future complications is insufficient. The test
 6 under Wisconsin law is whether these various future complications are “reasonably
 7 certain” to occur. The doctors’ testimony is clear: they could not say that Mrs. Tinlin is
 8 reasonably certain to incur future bleeding, hemoptysis, pneumothorax, death, additional
 9 complications with the filter, arrhythmias, cardiac failure, endocarditis, additional hernias,
 10 abscess, or hemorrhage into the lung. (SOF ¶¶ 24, 26, 28, 30, 34, 35.) As such, the
 11 plaintiffs cannot recover damages related to these issues, and summary judgment is
 12 warranted.

13 **V. Conclusion.**

14 For these reasons, and for the reasons discussed in Bard’s Motion, Bard
 15 respectfully requests that this Court grant Bard’s Motion for Summary Judgment.

16 RESPECTFULLY SUBMITTED this 15th day of March, 2019.

17
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CERTIFICATE OF SERVICE

I hereby certify that March 15, 2019, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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